

## REMARKS

### Claim Status & Amendments

Upon entry of this Amendment, claims 1-4, 7-10 and 19-22 are pending, of which claim 1 is independent. Claims 5 and 6 are cancelled without prejudice to or disclaimer of the underlying subject matter. Of the pending claims, claims 1-3, and 19-22 are currently amended. Claim 1 is amended to incorporate the features of claims 5 and 6, and to recite “a microorganism comprising RNA”. Claims 1 and 2 are amended to replace “containing” with “comprising”. Claim 3 is amended to recite that “autolysis in a) is initiated by at least one of: i) damaging the microbial cell walls; and ii) partially disrupting the microbial cell walls.” Claim 4 is amended to recite that “damaging the microbial cell walls, partially disrupting the microbial cell walls, or both is performed enzymatically.” Claims 19-22 are amended to depend from claim 1. Support for the amendments may be found at least at page 5, lines 4-13, and page 5, lines 20-25 of the Specification as-filed, for example. Thus, no new matter has been added. Reconsideration and withdrawal of the outstanding rejections and allowance of the application is respectfully requested in view of the following remarks.

### ***Rejections Under 35 U.S.C. § 112, second paragraph***

#### Claims 1-10 & 19-22

Claims 1-10 and 19-22 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

The Office stated that “[t]he term ‘substantial part of the RNA remains in a form degradable’ in claim 1 ... is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.”<sup>1</sup>

The specification, however, states the following:

In the process of the invention the conditions used in the autolytic process are such that a substantial part of the RNA remains in a form degradable into 5'-ribonucleotides. In this context, with “substantial part of the RNA” is meant preferably at least 50%, more

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<sup>1</sup> Office Action, 2 (Apr. 13, 2011).

preferably at least 60%, most preferably at least 70%. Thus, the RNA does not need to remain fully intact during the autolytic process, but at least a substantial part of the RNA should remain in a form degradable into 5'-ribonucleotides.<sup>2</sup>

Thus, Applicant respectfully submits that the phrase is defined by the specification, that the specification provides a standard for ascertaining the requisite degree, and that one of ordinary skill in the art would be reasonably apprised of the scope of the invention. Nevertheless, in the interest of advancing prosecution on the merits, the claim 1 phrase “substantial part of the RNA remains in a form degradable” is amended to read “at least 50% of the RNA remains in a form degradable”.

The Office stated that “[t]he term ‘substantial part of the RNA remains associated with the cell wall fraction’ in claim 1 ... is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The specification, however, states the following:

In the process of the invention the conditions used in the autolytic process are such that during the autolysis a substantial part of the RNA remains associated with the cell wall fraction, i.e. remains inside the damaged cells and/or bound to the cell walls or fragments thereof. In this context, with “substantial part of the RNA” is meant preferably at least 20%, more preferably at least 30%, most preferably at least 40%. Generally up to 90% of the RNA may remain associated with the cell wall fraction.<sup>3</sup>

Thus, Applicant respectfully submits that the phrase is defined by the specification, that the specification provides a standard for ascertaining the requisite degree, and that one of ordinary skill in the art would be reasonably apprised of the scope of the invention. Nevertheless, in the interest of advancing prosecution on the merits, the claim 1 phrase “substantial part of the RNA remains associated with the cell wall fraction” is amended to read “at least 20% of the RNA remains associated with the cell wall fraction”.

The Office asserted that claim 1 allegedly is “incomplete for omitting essential steps, such omission amounting to a gap between the steps.”<sup>4</sup> According to the Office,

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<sup>2</sup> Specification, 5:4-9 (Jun. 28, 2006).

<sup>3</sup> *Id.* at 5:20-25 (Jun. 28, 2006).

<sup>4</sup> Office Action, 3.

[t]he omitted steps are: the conditions that cause “a substantial part of the RNA remains in a form degradable into 5'-ribonucleotides and at which a substantial part of the RNA remains associated with the cell wall fraction” which are found in a) of the claim 1. The steps recited in parts b) and c) of the claim are separation, recovery and RNA conversion steps. The steps recited in parts b) and c) are not conditions at which “a substantial part of the RNA remains in a form degradable into 5'-ribonucleotides and at which a substantial part of the RNA remains associated with the cell wall fraction”.<sup>5</sup>

Applicant respectfully submits that the conditions which cause “a substantial part of the RNA [to] remain[ ] in a form degradable into 5'-ribonucleotides and ... which [cause] a substantial part of the RNA [to] remain[ ] associated with the cell wall fraction,” and the determination of said conditions, are well within the knowledge of one of ordinary skill in the art. As explained by the specification:

The conditions applied in the autolysis to ensure that a substantial part of the RNA remains in a form degradable into 5-ribonucleotides and that a substantial part of the RNA remains associated with the cell wall fraction, will be generally dependent on the microorganism used. These conditions can be easily determined by those skilled in the art by varying process parameters like temperature and/or pH and/or the time period at which a particular temperature and/or pH is maintained during autolysis and subsequently determining the effect of such process parameter(s) on the amount of RNA which remains in a form degradable into 5-ribonucleotides and/or which remains associated with the cell wall fraction.

In particular the first phase of autolysis is performed at a particular pH range combined with a particular temperature.

For instance, the conditions applied in the autolysis of *Saccharomyces cerevisiae* to ensure that a substantial part of the RNA remains in a form degradable into 5'-ribonucleotides and that a substantial part of the RNA remains associated with the cell wall fraction are such that the pH in the first phase of the autolysis is between 4.5-9 and/or the temperature is between 50-65°C. Preferably the first 8 hours of the autolysis, more preferably the first 4 hours of the autolysis, are performed at a pH of 4.5-5.5 and at a temperature of 57-65°C, or at a pH 5.5-9 and a temperature of 50-65°C.

The conditions to be kept after the first phase of the autolysis are less critical. After the first phase the pH is generally kept between 4 and 10 and the temperature is generally kept between 40°C and

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<sup>5</sup> *Id.*

70°C. In general the duration of the autolytic process including the first phase is at most 24 hours.<sup>6</sup>

The Office noted that the phrase “the RNA” in line 4 of claim 1 lacked antecedent basis. Claim 1 now refers to “a microorganism comprising RNA” before the phrase “the RNA,” providing antecedent basis.

The Office stated that the phrase “and/or” in claim 3 allegedly rendered the claim indefinite “because it is unclear whether the limitation following the phrase is part of the claimed invention.”<sup>7</sup> Claim 3 is amended to recite “wherein autolysis in a) is initiated by damaging the microbial cell walls, partially disrupting the microbial cell walls, or both.”

The Office stated that “[t]he term ‘partial’ [in claim 3] is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.”<sup>8</sup> The specification states:

The autolytic process is initiated by damaging and/or partially disrupting the microbial cell walls. This way the cells are partially opened and at least some of the cell content is released. In order to damage and/or partially disrupt the microbial cell walls, the cells are treated chemically, mechanically or enzymatically using methods known to those skilled in the art.<sup>9</sup>

Thus, one of ordinary skill would recognize that the claim 3 phrase “partially disrupting the microbial cell walls” requires that “at least some of the cell content is released,” as stated in the specification.

Consequently, Applicant respectfully submits that claims 1-10 and 19-22 are not indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1-10 and 19-22 under 35 U.S.C. § 112, second paragraph.

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<sup>6</sup> Specification, 6:14-7:2.

<sup>7</sup> Office Action, 3.

<sup>8</sup> *Id.* at 3.

<sup>9</sup> Specification, 4:10-14.

***Non-Statutory Obviousness-Type Double Patenting Rejections***

Claims 1, 2, 4, 10, 19, & 20 over claims 6, 13, 21, 22, 26, & 27 of co-pending U.S. Pat. Appl. No. 10/541,194

Claims 1, 2, 4, 10, 19, and 20 were provisionally rejected under the judicially-created doctrine of non-statutory obviousness-type double patenting as being unpatentable over claims 6, 13, 21, 22, 26, and 27 of co-pending U.S. Pat. Appl. No. 10/541,194. Applicants respectfully request that this rejection be held in abeyance until the final disposition of U.S. Pat. Appl. No. 10/541,194.<sup>10</sup>

***Conclusion***

In view of the remarks above, Applicant respectfully submits that the stated grounds for rejection have been properly addressed and that all of the claims are patentable, and so request favorable action thereon. The Examiner is invited to contact the undersigned if any additional information is required.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-4254, under Attorney Docket No. 2919208-002000.

Respectfully submitted,

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<sup>10</sup> See, e.g., M.P.E.P. § 822.01.